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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,439	12/03/2003	John Jackson McAughey		5354

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,439	MCAUGHEY ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are indefinite because the term "elevated temperature" is vague and is not explicitly defined in the specification. It is noted that on page 2 of the specification a range of elevated temperatures are provided. It appears that the intended meaning of the term "elevated temperature" could be clarified by inclusion of the ranges cited on page 2 of the instant application.

Claims 5-8 are vague and indefinite, because it is unclear what are the intended means in which the recited apparatus can vaporize cannabis, cause cannabis to flow with a carrier gas, and generate seed nuclei particles. Although there are many known methods and devices used in the art to heat and/or vaporize compounds, a person of ordinary skill would be unable to ascertain from the instant claim language, what Applicant had intended as the device/component to accomplish said function in the recited apparatus. Furthermore, it is noted that a search of an apparatus lacking explicit components and only mentioning means of accomplishing certain functions may be burdensome.

The remaining claims are rejected as being dependent upon a rejected claim.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the "means: for vaporizing cannabis, causing the cannabis to flow with the carrier gas, and to generate a seed nuclei particle." A skilled artisan in the art would be unable to ascertain what Applicant intended as the means of accomplishing these different functions within the claimed apparatus. Furthermore, it is noted that a search of an apparatus lacking explicit components and only mentioning means of accomplishing certain functions may be burdensome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensley et al. (US 2003/0062042).

Wensley does not anticipate the cited claims, because Wensley does not explicitly teach a method in which at a lower temperature the vapor would be supersaturated.

Wensley teaches **a method and device are provided to generate an aerosol having a desired particle sizes, i.e., from molecular to about 10 microns**, which can be used to effectively deliver a physiologically active compound to organs and tissues. The aerosol is formed through **vaporization of the compound while mixing the resulting vapor with a gas**, in a ratio, to form the desired particle size when a stable concentration of particles in the gas is reached (abstract).

Wensley teaches that an aerosol is defined as an assembly of a liquid or solid particles suspended in a gaseous medium and that aerosols of appropriate particle size can be used to deliver drugs to organs and tissues, such as lung and mucosa [0003].

Wensley teaches that his method creates a mixture of vapor and gas in a ration suitable to generate aerosol particles of a desired size range and effective for administration to a patient.

The terms "air", "mixing gas", "dilution gas" and "carrier gas" are interchangeable [0018]. Wensley's aerosols may be generated in one of several alternative routes, including, (1) **heating to vaporize the compound while simultaneously mixing it with a gas in a ratio to permit condensation and aggregation into particles of the desired size**; **(2) heating to vaporize the compound to create a pure vapor to permit condensation and aggregation into particles of the desired size; (3) heating to vaporize the compound to create a pure vapor, followed by introduction of the vapor to a gas in a ratio to permit condensation and aggregation into particles of the desired size; and (4) mixing the aerosols created by the means in 1, 2, or 3 above with additional gas to arrest aggregation and stabilize particle size** [0019]-[0023].

Wensley teaches that his methods and device physiologically active compounds may be volatized without medicinally significant degradation of the resulting vapors to form aerosols [0055] and that limiting the exposure time of a compound to an elevated temperature is critical [0059]. **The compound is moved quickly through a heating/mixing zone to facilitate a rapid temperature rise on the order of 2,000 °C/s**. Compounds thus reach vaporization temperatures in ten's of milliseconds and quickly escape as vapors from thin layers of deposited compound, **move into a cool carrier gas stream** that flows across the surface of the compound, and lose their thermal energy upon collision with molecules of the cooler carrier gas [0059].

Wensley teaches that a stable particle of the ultra fine or fine size range is produced and a predetermined amount of compound in its vapor-state can be mixed into a predetermined volume of a carrier gas in a ratio to give particles of a desired size as the number concentration of the aerosol itself becomes stable [0063]. The ratio of vaporized compound to the volume of mixing air (i.e. carrier gas) can be controlled by a number of methods including, regulating the

vaporization rate of the compound (e.g. **changing the amount of compound introduced into a heating region**) [0065]. Changing the amount of compound introduced into a heating region reads on introducing a compound to be vaporized into a vaporizing means at a controlled rate (i.e. claim 6). In an eighth embodiment, Wensley's apparatus has **a moving heating zone** without any moving parts, wherein a heat gradient traverses the length of the device, and as the heating zone moves, exposed portions of the compound are subsequently heated and vaporize [0113]. Exemplary compounds that can be vaporized in accordance with Wensley's invention include **cannabinoids extracts from cannabis and THC** [0131]. THC is tetrahydrocannabinoid and is recognized as one of the active agents attributed to inhaled cannabis smoke.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that Wensley's invented method incorporates the step of causing cannabis vapor and carrier gas to flow to a region of lower temperature, because Wensley teaches that the vaporized compound (e.g. "cannabis") quickly escape into a cool carrier gas stream (i.e. the carrier gas is flowing). It would have been apparent that the cooler carrier gas would lower the temperature of the vaporized cannabis and move the cannabis to a region of lower temperature. The lowering of the temperature of the cannabis vapor would have been expected to result in the formation of an aerosol (i.e. a liquid suspended in a gas), because cooling due to interaction with the carrier gas would lower the cannabis vapor temperature below the boiling point of cannabis. Furthermore, Wensley's invented device and method are directed towards the generation of aerosols. It would have been apparent to a skilled artisan that the cannabis vapor would have been supersaturated, because the vapor pressure of cannabis would have been expected to be higher than that of cannabis due to the removal of cannabis vapor by the carrier gas from above

the surface of the heated cannabis. Furthermore, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 2, 4, and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensley et al. (US 2003/0062042) as applied to claims 1 and 5-6 above, and further in view of McKinney (U.S. Patent No. 4,279,824) (USPN '824).

The teachings of Wensley have been set forth above.

Wensley lacks the teaching of seed nuclei generated by passing gas over a bath of molten material and an apparatus comprising a vaporizing means for another liquid whose vapor is mixed with the cannabis vapor.

McKinney teaches **a method and apparatus for processing herbaceous plant materials** including the plant **cannabis**, by **heating** it to within a specific temperature range for a predetermined period of time within a novel processing apparatus (title and abstract). The cannabis varieties, which may be processed, include *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*. The plant material is heated within an atmosphere of controlled oxygen content to a temperature of up to 120 °C (col. 3, lines 5-12).

McKinney teaches that Cannabis is known to contain the chemicals delta-9 tetrahydrocannabinol and cannabidiol, 95% of which in nature are present in the precursor acid

states. Both delta-9 tetrahydrocannabinol and cannabidiol exhibit no psychoactive properties in their acid forms. Before any psychoactive activities are affected, delta-9 tetrahydrocannabinol and cannabidiol must be decarboxylated. This is generally accomplished by the administration of heat to the point at which the carboxylic acid radical is removed from the molecule (col. 1, lines 37-67 and col. 2, lines 11-16). An object of McKinney's invention is to provide a method as aforesaid wherein the plant cannabis is subjected to a controlled decarboxylation to convert cannabinolic acid to delta-9 tetrahydrocannabinol without oxidation of the resulting product (col. 3, 51-55).

In Figure 2, McKinney illustrates a device wherein the heating means (18) may comprise a **circular heating coil** (20), which is provided with **electrical connection to a temperature responsive switching means** (22). The responsive switch may comprise a thermostatic switch, constructed to interrupt the supply of electrical current to the heating element (20) (i.e. the heating coil) when the temperature of the container reaches the level in excess of that required for efficient non-destructive heating of the plant material (col. 5, lines 25-39). An electrical heating coil reads on an electrical wire. It is noted that McKinney states, "a fluid medium, such as ordinary tap water, may then be placed inside container 2 to a level wherein it will reside just below the bottom of basket 10" (col. 5, lines 20-24). The basket contains the cannabis.

McKinney teaches that where water is the fluid medium, the heating process generates a substantial amount of pressure, which must be vented using a one-way air vent (26) (col. 5, lines 54-59). The air vent provides a means for the egress of moisture (i.e. water vapor) and vapor (col. 6, lines 37-40).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Wensley and McKinney, because both teach methods of processing materials derived from cannabis plants. A skilled artisan would have been further motivated to combine the teachings of Wensley and McKinney to obtain a method and apparatus to convert the contents of the cannabis plant to the more active derivatives (e.g. delta-9 tetrahydrocannabinol and cannabidiol). A skilled artisan would have had a reasonable expectation of success upon combination of the prior art references, because Wensley teaches a method and an apparatus capable of generating aerosols from cannabinoids derivatives and THC and McKinney teaches an apparatus and method for processing cannabis, which obviously is comprised of cannabinoids derivatives and THC. Incorporation of McKinney's teachings into the method and apparatus taught by Wensley would have yielded a device and method in which the cannabis vapor is in admixture with water vapor as well as a means to generate water vapor. It would have been apparent to a skilled artisan that a molten material is one corresponding to a melted solid. Liquid water is the melted form of ice, a solid, and is therefore a molten material.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wensley et al. (US 2003/0062042) in view of McKinney (U.S. Patent No. 4,279,824) (USPN '824) as applied to claims 2, 4, and 7-8 above, and further in view of Torochtin et al. (DE 4003989; English abstract only).

The teachings of Wensley and McKinney have been set forth above.

Wensley and McKinney lack the teaching of the generation of seed nuclei by passing gas over a bath of molten sodium chloride.

Torochtin teaches the formation of a therapeutic atmosphere with sodium chloride crystals, which are entrained by a stream of air extracted from the atmosphere and heated to 600 °C. The resulting aerosol is especially useful for bronchial asthma treatment comparable with that produced in natural salt treatment mines (abstract).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Wensley, McKinney, and Torochtin, because both Wensley and Torochtin teach methods of generating aerosols. A skilled artisan would have been motivated to combine the teachings of Wensley and McKinney with those of Torochtin to obtain aerosols, which are especially useful in the treatment of bronchial asthma. It would have been apparent to a skilled artisan that heating the sodium chloride (NaCl) to its melting point would have been beneficial as this would generate NaCl aerosols that would be combined with the carrier gas and cannabis vapor flowing by and promote the generation of additional aerosol particles. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art teachings because both Wensley and Torochtin teach the generation of aerosols intended for the use in therapeutic treatments.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rabinowitz et al. (U.S. Patent No. 6,740,307) is relevant, because it teaches a method of delivery aerosolized active agent comprising heating a composition comprising the active to generate an active vapor and allowing the vapor to cool, thereby forming condensation aerosol particles.

Claims 1-8 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER